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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,997	03/19/2004	Gust H. Bardy	1201.1108102	8939

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/804,997

Applicant(s)

BARDY ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/14/06 (Response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 5, 10, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11-14, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/15/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I, Species III in the reply filed on 12/14/06 is acknowledged.

Specification

2. The specification contains references to parent applications by their application numbers. Some or all of these applications have since been issued or been abandoned. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-4 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 2, it is unclear what the word "proximally" means in the context of the claim. Does it face proximally to the proximal end of the lead, or does it face proximally to a proximal end of the electrode assembly, or does it face proximally with respect to some other structure?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6-9, 11 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilman (4,270,549).

Regarding claim 1, Heilman shows a canister containing circuitry for sensing and treating a heart rhythm irregularity, the canister sized and adapted for implantation to a patient; and a lead assembly coupled to the canister, the lead assembly having: a lead having proximal (28, 32) and distal ends, the proximal end adapted to be received by the canister, the distal end including an electrode assembly (10); and an electrode assembly having a proximal end and a distal end, the proximal end secured to the lead, the electrode assembly including an electrode surface (12) capable of delivering shocking energy to the patient and an opening (50) capable of receiving an insertion tool (Figs. 1, 3).

With respect to claim 2, Heilman shows the opening faces proximally.

Regarding claims 3, and 21, Heilman shows the electrode assembly has a front side (Fig. 1) and a back side (Fig. 3), wherein the electrode surface (12) is disposed on the front side and the opening (50) is disposed on the back side, the opening leading into a pocket defined by a piece of material (44) secured to the back side and having a closed distal portion (Figs. 1-3). With respect to claim 4, Heilman shows the electrode assembly further comprises a fin (52) secured to the backside, the fin disposed with respect to the piece of material (44) to at least

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partially define the opening (Col. 6, lines 47-56). The prior art does not disclose any structure on the front side of the electrode assembly that would impede sliding implantation over a patient's ribcage, therefore it is configured for sliding implantation over a patient's ribcage.

Regarding claim 6, Heilman shows the electrode assembly includes an electrode (12) and a molded cover (16, 14), the molded cover having a front side (16) and a back side (14), the front side adapted to define an electrode opening, wherein the electrode is disposed in the molded cover, the molded cover including a skirt portion extending around and over a portion of the electrode (12) to define the electrode opening and cover the edges of the electrode (Fig. 1).

With respect to claim 7, Heilman shows the electrode assembly further includes stitching (36) securing the electrode between the skirt portion of the molded cover (16) and the back side of the molded cover (14) (Figs 1-3).

Regarding claims 8-9, Heilman shows a piece of material (44) secured to the molded cover (16, 14) and defining the opening and the piece of material (44) defines the opening on the backside of the molded cover (14) (Figs. 1-3).

With respect to claim 11, Heilman shows the electrode assembly has a front shocking side (16, 12) and a back side (14), the electrode assembly further including a fin (52) on the back side, the opening defined on the fin.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11-14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman (4,270,549).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Regarding claim 12, Heilman shows an electrode assembly (10); and an elongated lead having a first end including a connector (28, 32) and a second end secured to the electrode assembly; wherein the electrode assembly includes: an electrode (12) having at least one outside edge; a molded cover (16, 14), the molded cover having a back portion (14) and a skirt portion (16); and means for receiving an insertion tool (50) secured to the molded cover; wherein the electrode assembly is configured such that the electrode (12) is received by the molded cover (16) to define an electrode surface surrounded by the skirt, the molded cover receiving and isolating the outside edge of the electrode (Figs. 1-3). Although Heilman fails to show the skirt portion and back portion are composed of one piece of material it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the apparatus of Heilman to integrate the skirt portion and back portion since it has been held "that the use of a one piece construction instead of the structure disclosed would be merely a matter of obvious engineering choice" *In re Larson*, 340 F.2d 965, 968 (CCPA 1965).

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Regarding claims 13-14, Heilman shows the means for receiving (50) comprises a piece of material (44) secured to the back portion of the molded cover (14) and is secured to with a fin (52) on the back portion, the piece of material (44) being secured over the fin (52) (Col. 6, lines 47-56).

Regarding claim 22, Heilman shows the electrode assembly has a front side (Fig. 1) and a back side (Fig. 3), wherein the electrode surface (12) is disposed on the front side and the means for receiving (50) is disposed on the back side (Figs. 1-3). The prior art does not disclose any structure on the front side of the electrode assembly that would impede sliding implantation over a patient's ribcage, therefore it is configured for sliding implantation over a patient's ribcage.

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alfandari (EPO 0134367 A1) shows an electrode structure with an electrode on a front surface and an opening on the back surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen D. Mullen
Patent Examiner - Temp. Full
Signatory Authority
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kdm